

WHAT IS CLAIMED IS:

- 5 1. A process for stabilizing a blood protein solution comprising:  
(a) providing a blood protein solution;  
(b) adding to the solution hydroxypropyl- $\alpha$ -cyclodextrin in an amount  
sufficient to form a stable complex with the protein; and  
(c) lyophilizing the solution of step (b) to form a lyophilized  
10 protein/hydroxypropyl- $\alpha$ -cyclodextrin complex.
2. The process according to claim 1, further comprising reconstituting the  
lyophilized protein/hydroxypropyl- $\alpha$ -cyclodextrin complex.
- 15 3. The process according to claim 1, further comprising heating the blood protein  
solution, before or after adding hydroxypropyl- $\alpha$ -cyclodextrin, at least about 60°C for a time  
sufficient to inactivate any viruses present in the protein/hydroxypropyl- $\alpha$ -cyclodextrin complex.
- 20 4. The process according to claim 3 wherein the blood protein solution is heated for  
at least about 10 hours.
5. The process according to claim 3 wherein the blood protein solution is heated to  
a temperature of at least about 80°C for at least about 72 hours.
- 25 6. The process according to claim 3 wherein the blood protein solution is heated to  
about 100°C for at least about 1 hour.
7. The process according to claim 1, further comprising subjecting the blood protein  
solution, before or after adding the hydroxypropyl- $\alpha$ -cyclodextrin, to a solvent detergent viral  
30 inactivation step.
8. The process according to claim 1, wherein the hydroxypropyl- $\alpha$ -cyclodextrin is  
present in the protein solution in an amount ranging from about 0.5% wt/vol. to about 15%  
wt/vol.

9. The process according to claim 1, wherein the hydroxypropyl- $\alpha$ -cyclodextrin is present in the protein solution in an amount ranging from about 1% wt/vol. to about 12% wt/vol.

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10. The process according to claim 2, wherein the protein is present in the reconstituted protein/hydroxypropyl- $\alpha$ -cyclodextrin complex in an amount greater than about 0.1% wt/vol.

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11. The process according to claim 2 wherein the protein is present in the reconstituted protein /hydroxypropyl- $\alpha$ -cyclodextrin complex in an amount from about 1% to about 8 %.

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12. The process according to claim 1 wherein the protein is selected from the group consisting of albumin, Factor II, Factor VII, Factor VIII, Factor IX, Factors X and X<sub>a</sub>, fibrinogen, antithrombin III, transferrin, haptoglobin, gamma globulins, fibronectin, protein C, protein S, thrombin and C1-inhibitor.

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13. The process according to claim 1, wherein the protein is fibrinogen.

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14. The process according to claim 12, wherein the hydroxypropyl- $\alpha$ -cyclodextrin is present in the protein solution in an amount ranging from about 0.5% wt/vol. to about 15% wt/vol.

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15. The process according to claim 12, wherein the hydroxypropyl- $\alpha$ -cyclodextrin is present in the protein solution in an amount ranging from about 2% wt/vol. to about 12% wt/vol.

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16. The process according to claim 12, wherein the fibrinogen is present in the reconstituted protein/hydroxypropyl- $\alpha$ -cyclodextrin complex in an amount greater than about 1% wt/vol.

17. The process according to claim 12, wherein the protein is fibrinogen, and the fibrinogen is present in the reconstituted protein /hydroxypropyl- $\alpha$ -cyclodextrin complex in an amount from about 3% wt/vol. to about 10% wt/vol.

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18. A process for stabilizing a fibrinogen solution comprising:
- (a) providing a fibrinogen solution;
  - 5 (b) adding to the solution hydroxypropyl- $\alpha$ -cyclodextrin in an amount sufficient to form a stable complex with the protein;
  - (c) lyophilizing the solution of step (b) to form a lyophilized fibrinogen/hydroxypropyl- $\alpha$ -cyclodextrin complex; and
  - 10 (d) reconstituting the lyophilized fibrinogen/hydroxypropyl- $\alpha$ -cyclodextrin complex.

19. A lyophilized blood protein/hydroxypropyl- $\alpha$ -cyclodextrin complex prepared by:
- (a) providing a blood protein solution;
  - 15 (b) adding to the solution hydroxypropyl- $\alpha$ -cyclodextrin in an amount sufficient to form a stable complex with the protein; and
  - (c) lyophilizing the solution of step (b) to form the lyophilized blood protein/hydroxypropyl- $\alpha$ -cyclodextrin complex.

20. A blood protein product prepared by:
- (a) providing a blood protein solution;
  - 20 (b) adding to the solution hydroxypropyl- $\alpha$ -cyclodextrin in an amount sufficient to form a stable complex with the protein;
  - (c) lyophilizing the solution of step (b) to form a lyophilized protein/hydroxypropyl- $\alpha$ -cyclodextrin complex; and
  - 25 (d) reconstituting the lyophilized protein/hydroxypropyl- $\alpha$ -cyclodextrin complex.

21. A fibrinogen product prepared by:
- (a) providing a fibrinogen solution;
  - 30 (b) adding to the solution hydroxypropyl- $\alpha$ -cyclodextrin in an amount sufficient to form a stable complex with the protein;
  - (c) lyophilizing the solution of step (b) to form a lyophilized fibrinogen/hydroxypropyl- $\alpha$ -cyclodextrin complex; and
  - 35 (d) reconstituting the lyophilized fibrinogen/hydroxypropyl- $\alpha$ -cyclodextrin complex.

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22. A blood protein product comprising a lyophilized solution of a stable complex of protein and hydroxypropyl- $\alpha$ -cyclodextrin.

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23. The product according to claim 22, wherein the hydroxypropyl- $\alpha$ -cyclodextrin is present in the solution in an amount ranging from about 0.5% wt/vol. to about 15% wt/vol.

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24. The product according to claim 22, wherein the hydroxypropyl- $\alpha$ -cyclodextrin is present in the solution in an amount ranging from about 1% wt/vol. to about 12% wt/vol.

25. The product according to claim 22, wherein the blood protein is fibrinogen.

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26. A stabilized blood protein solution comprising a complex of the blood protein and hydroxypropyl- $\alpha$ -cyclodextrin.

27. The solution according to claim 26, wherein the protein is present in the complex in an amount greater than about 3% wt/vol.

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28. The product according to claim 26, wherein the hydroxypropyl- $\alpha$ -cyclodextrin is present in the solution in an amount ranging from about 0.5% wt/vol. to about 15% wt/vol.

29. The process according to claim 26, wherein the hydroxypropyl- $\alpha$ -cyclodextrin is present in the solution in an amount ranging from about 1% wt/vol. to about 12% wt/vol.

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30. The product according to claim 26, wherein the blood protein is fibrinogen.

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